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### MAILING CERTIFICATE

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May 12, 2006  
Date

by Kay Bulen  
Signature

Kay Bulen  
Printed Name

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Widschwendter

Serial No.: 10/575,753

International Filing Date: October 14, 2004

For: PROGNOSTIC AND DIAGNOSTIC MARKERS FOR CELL PROLIFERATIVE  
DISORDERS OF THE BREAST TISSUES

Art Unit:

Examiner:

Docket No.: 47675-183

Date: May 11, 2006

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

### INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the requirements in 37 C.F.R. § 1.56, and in conformance with 37 C.F.R. 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement. Applicant respectfully requests that the Examiner: (1) consider the following documents during the course of his or her examination of the above-identified patent application, and (2) list the following documents in the References Cited section of any patent that may issue from the above-identified patent application.

Applicant cites 15 references listed on the attached substitute for form PTO-1449. The

order of these references should not be construed to suggest their relative pertinence. The Examiner is encouraged to review the entire disclosure of each reference in order to draw his or her own conclusions concerning the pertinence of the references to the claimed subject matter of this application. The filing of this Information Disclosure Statement should not be construed to suggest that a patentability search has been made or that the cited references are prior art or are considered to be material to patentability.

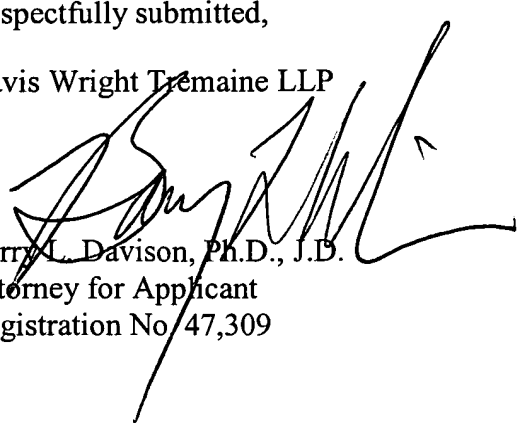
These documents came to the attention of the Applicants through the International Search Report issued in the PCT application from which this U.S. application was nationalized. A copy of this Search Report is also included.

Applicant respectfully requests consideration of the foregoing documents during examination of the above-identified patent application. Applicant has enclosed a completed Information Disclosure Statement by Applicant and copies of the non-US patent and non-patent literature documents.

This Information Disclosure Statement is being filed prior to issuance of the first Office Action. No fee is believed due. If any fee is deemed due, the Commissioner is authorized to charge Deposit Account 04-0258 of Davis Wright Tremaine LLP. A copy of this document is enclosed.

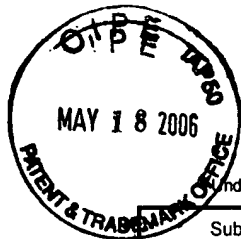
Respectfully submitted,

Davis Wright Tremaine LLP



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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 3

**Complete if Known**

Application Number 10/575,753

Filing Date October 14, 2004

First Named Inventor Widschwendter

Art Unit

Examiner Name

Attorney Docket Number 47675-183

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1	US-6,265,171	07-24-2001	Herman et al.	
	A2	US-2002/0164715	11-07-2002	Ji et al.	
	A3	US-2003/0138783	07-24-2003	Sukumar et al.	
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	A4	WO 01/75172	10-11-2001	University of Southern California		
	A5	WO 02/081749	10-17-2002	University of Southern California		

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformation with MPEP 609. Draw line through citation if not in conformation and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04 <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard St. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to compete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	
				Filing Date	
				First Named Inventor	
				Art Unit	
				Examiner Name	
Sheet	2	of	3	Attorney Docket Number	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A6	AGATHANGGELOU et al., Methylation associated inactivation of <i>RASSF1A</i> from region 3p21.3 in lung, breast and ovarian tumours, <i>Oncogene</i> 20:1509-1518, 2001	
	A7	BURBEE et al., Epigenetic Inactivation of <i>RASSF1A</i> in Lung and Breast Cancers and Malignant Phenotype Suppression, <i>J. Natl. Cancer Inst.</i> 93(9):691-699, 2001	
	A8	LEON et al., Free DNA in the Serum of Cancer Patients and the Effect of Therapy, <i>Cancer Res.</i> 37:646-650, 1977	
	A9	MANNING et al., The Role of Four Oestrogen-responsive Genes, pLIV1, pS2, pSYD3 and pSYD8, in Predicting Responsiveness to Endocrine Therapy in Primary Breast Cancer, <i>Eur. J. Cancer</i> 29A(10):1462-1468, 1993	
	A10	MUELLER et al., DNA Methylation in Serum of Breast Cancer Patients: An Independent Prognostic Marker, <i>Cancer Res.</i> 63:7641-7645, 2003	
	A11	NASS et al., Aberrant Methylation of the Estrogen Receptor and E-Cadherin 5' CpG Islands Increases with Malignant Progression in Human Breast Cancer, <i>Cancer Res.</i> 60:4346-4348, 2000	
	A12	VAN'T VEER et al., Gene expression profiling predicts clinical outcome of breast cancer, <i>Nature</i> 415:530-536, 2002	
	A13	VAN DE VIJVER et al., A Gene-Expression Signature as a Predictor of Survival in Breast Cancer, <i>New Engl. J. Med.</i> 347(25):1999-2009, 2002	
	A14	VIRMANI et al., Aberrant Methylation of the <i>Adenomatous Polyposis Coli (APC)</i> Gene Promoter 1A in Breast and Lung Carcinomas, <i>Clin. Cancer Res.</i> 7:1998-2004, 2001	
	A15	YAN et al., Differential Distribution of DNA Methylation within the <i>RASSF1A</i> CpG Island in Breast Cancer, <i>Cancer Res.</i> 63:6178-6186, 2003	

Examiner Signature		Date Considered	
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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